

**REMARKS****The Rejection of Claims 30-35 and 38-52 Under 35 U.S.C. §112, Second Paragraph**

Claims 30-35 and 38-52 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

The Examiner finds that claims 30-35 and 38-52 are indefinite. This rejection is based on the phrase “symptoms associated with bacterial vaginosis” which is found to be unclear. Claims 30 and 59 are hereby amended to further clarify the meaning of these claims indicating that the described medicament is administered to an individual having one or more symptoms of bacterial vaginosis. Applicant submits that the claims are clear and respectfully requests withdrawal of the rejection and allowance of the claims.

**The Rejection of Claims 31-35, 38-42, 53, 55 and 57 under 35 U.S.C. §102(b)**

Claims 31-35, 38-42, 53, 55 and 57 stand rejected under 35 U.S.C. §102(b) as being anticipated by Greco et al., U.S. Patent No. 5,084,277.

The Examiner finds that claim 30 lacks novelty over Greco et al. (US 5,084,277) because the composition disclosed in Greco et al. would inherently perform the treatment and/or amelioration described in the present invention.

Applicant respectfully disagrees with this assertion. The composition described in Greco et al. is described to be for treatment of progesterone deficiency. The composition is described to contain a therapeutic amount of progesterone, an excipient and a disintegrant (col 3, lines 61-62). The active ingredient in said composition is accordingly progesterone and lactose is merely used as an excipient.

The Examiner finds that Greco et al. administer the same composition to the same group of patients and refers to col. 6, lines 1 to 50. However, the reference to col. 6, lines 1-50 does not teach anything regarding the patients to be treated. The composition disclosed in Greco et al. is rather described to be suitable for treating a variety of progesterone deficiency conditions (col. 4, lines 52-57) and the patients disclosed in Greco et al. are not described to be having any symptoms of bacterial vaginosis. The individuals to be treated according to amended claim 30 are individuals

having one or more symptoms of bacterial vaginosis and accordingly not disclosed or suggested in Greco et al. Accordingly, independent claim 30, and all claims dependent thereon, is submitted to be novel over Greco et al. and Applicant respectfully requests withdrawal of the rejection and allowance of the claims.

Independent claim 53 is hereby amended to emphasize that the pharmaceutical composition of amended claim 53 does not contain progesterone. Applicant finds no indication that the Greco et al. reference describes a composition without progesterone. Accordingly, independent claim 53 and all claims dependent thereon is submitted to be novel over Greco et al. and Applicant respectfully requests withdrawal of the rejection and allowance of the claims. Furthermore, based on the Greco et al. reference here would be no expectation of success by removing the active ingredient progesterone and employing lactose as active ingredient for treatment of the patients disclosed in Greco et al. The ordinary skilled artisan would not, from the teachings disclosed in Greco et al., be motivated to adjust the content of the composition to such an extent that the active ingredient progesterone was removed from the composition. Accordingly claim 53 and all claims dependent thereon is non-obvious over Greco et al.

**The Rejection of Claims 54, 56 and 59-61 under 35 U.S.C. §103(a)**

Claims 54, 56 and 59-61 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Greco et al., U.S. Patent No. 5,084,277.

The Examiner finds that it would be obvious to combine the composition disclosed in Greco et al. with other medicaments or substances such as antifungal or antibacterial agents in order to treat progesterone deficiency by administering Greco et al.'s composition and to simultaneously, sequentially or separately treat associated conditions or other vaginal conditions such as bacterial vaginosis.

Claim 54 is dependent on claim 53 which has been amended to exclude the presence of progesterone in the pharmaceutical composition of the present invention. Accordingly the kit-of-parts described in claim 54 does not contain progesterone. As described above, Greco et al. disclose a composition for treatment of progesterone deficiency conditions (col. 4, lines 52-57) and nowhere is the ordinary skilled artisan, from the teachings disclosed in Greco et al., motivated to adjust the

content of the composition to such an extent that the active ingredient progesterone is removed from the composition.

Amended claim 59 is directed to treatment of individuals having one or more symptoms associated with bacterial vaginosis. As described above treatment of such individuals is not disclosed or suggested in Greco et al. Accordingly claim 59 and all claims dependent thereon are non-obvious over Greco et al. Applicant respectfully requests withdrawal of the rejection and allowance of the claims.

The present invention is based on the finding that saccharides (such as lactose) may be used to treat bacterial vaginosis. Accordingly the active ingredient of the present invention is the saccharide and Examples 1-8 in the application as filed describes 8 different embodiments of the present invention. In example 9 it is described how administration of the lactose suspension of example 8 removes the symptoms of bacterial vaginosis (discomfort and vaginal secretions of fishy odor) and lowered the vaginal pH.

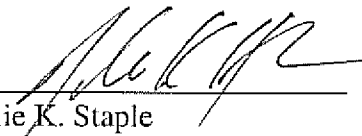
Accordingly, Applicant submits that Greco et al. does not teach or suggest all aspects of claims 54, 56, 59-61 and all claims dependent thereon and no prima facie case of obviousness has been established. Applicant submits that the claims are not obvious in light of Greco et al. and respectfully requests withdrawal of the rejections and allowance of the claims.

### **Summary**

By this amendment, claims 30, 53 and 59 have been amended, and new dependent claims 62 and 63 have been added. Claims 30-35, 38-57 and 59-63 are pending in the present application and presented herein for reconsideration of the Examiner. Questions regarding this application may be directed to the undersigned attorney at the telephone number provided below.

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Respectfully submitted,

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